

EA-REF885-50 **STERILE** DUKAL PVP SOLUTION IN A **STERILE** PEEL POUCH

I can address the following concern regarding the statement located on the labeling of the secondary packaging of # EA-REF885-50, STERILE PVP ¾ OZ. The statement in question “CONTENTS OF FOIL PACKETS, BOTTLES, OR AMPULES HAVE NOT BEEN TERMINALLY STERILIZED”.

To fully understand the process here is the background information on the process. As a contract packager and sterilizer, Sterling Medical Products purchases the STERILE PVP ¾ OZ. from Dukal. We private label the secondary packaging for Euro American IP, LLC.

Each ¾ oz. packet is packaged in a foil packet and is terminally sterilized using Gamma Radiation. Both the contents (PVP Solution) and the outer primary packaging (Foil Packet) are sterilized using this method.

For customers that want to drop the # EA-REF885-50, STERILE PVP ¾ OZ. onto a sterile field, Sterling Medical Products provides secondary packaging. We insert the Dukal Sterile Foil Packets into a 4” x 9” peel pouch. Each peel pouch is sealed in our clean room and then the secondary sterilization is performed. The secondary sterilization method we use is EO (Ethylene Oxide).

The reason we put the statement “CONTENTS OF FOIL PACKETS, BOTTLES OR AMPULES HAVE NOT BEEN TERMINALLY STERILIZED” on the secondary packaging is that the EO gas cannot penetrate through the foil packet. The EO gas can only penetrate the inside of the secondary packaging. Our processing does not affect the sterility of product inside of closed foil packets, bottles, or ampoules and therefore enables the product to be dropped onto a sterile field.

We always include a copy of the COS (Certificate of Sterility) that contains the LOT Number, which we provide with each shipment to Euro American IP, LLC. Each shipment has a LOT Number has an Expiration Date of 2 years.

Hope the above information is helpful. If there is any additional information needed don't hesitate to reach out EuroAmerican IP, LLC.

Ryan Russell
Midwest Sales Director

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MEDICAL.

Website: www.sterlingmedproducts.com